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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,696	03/04/2002	Dov Borovsky	UF-214XCD1	5384

23557 7590 02/28/2005

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,696	BOROVSKY, DOV	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-29 and 39-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-29 and 39-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 12 October 2004 is acknowledged and entered. Following the amendment, claims 1-24 and 30-38 are canceled, claim 25 is amended, and the new claims 39-50 are added.

Currently, claims 25-29 and 39-50 are pending and under consideration.

Withdrawal of Objections and Rejections:

The rejection of claims 25-29 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

Declaration

The declaration under 37 CFR 1.132 filed on 12 October 2004 is acknowledged, and it is insufficient to overcome the following rejection of claims 25-29 based upon lack of utility under 35 U.S.C. 101, and lack of enablement under 35 U.S.C. 112, first paragraph, as set forth in the last Office action mailed on 03 May 2004, and for the reasons below.

The Declaration merely provides details of the method used to isolate the peptide of SEQ ID NO:2, i.e., the "complementary peptide approach". Items 3 and 4 of the declaration provide the background of the complementary peptide approach by citing the prior art, indicating that it has been found that many peptides complementary to hormones including ACTH, ... bind the appropriate hormone, and that the complementary peptide for TMOF hormone (FOMT) was determined by such methods. Item 5 of the declaration suggests that FOMT competes with the TMOF gut receptor, and specifically binds with the TMOF hormone. Items 6 and 7 of the declaration states that FOMT behaves as a synthetic receptor in effectively binding TMOF, and describes the isolation of SEQ ID NO:1 using degenerate oligonucleotide sequence based on the amino acid sequence of FOMT, wherein SEQ ID NO:1 is from a cDNA library of the mosquito, and has 378 nucleotides and the polyA end. The applicant further asserts that the method of isolation provides evidence of the claimed receptor's utility, e.g., TMOF binding capability, and one skilled in the art would appreciate the functional characteristics of the subject invention

(item 8). However, the declaration is insufficient to overcome the rejection because it provides no evidence as to whether the present SEQ ID NO:2 would bind to TMOF or analogs thereof. Supposedly, the present SEQ ID NO:2 is a "TMOF receptor" and the "complementary peptide approach" represents an alternative way for sequence prediction and receptor synthesis, however, as the polypeptide is not the result of direct isolation (i.e., protein isolation from its natural sources, or gene cloning using a sequence encoding a family member, for example), nor it is a complete sequence of a TMOF receptor, confirmation of TMOF binding capability would be necessary, as those demonstrated in the prior art cited by applicants. For example, Bost et al. (Proc. Natl. Acad. Sci. USA, 1985, 82:1372-1375) teaches a ACTH receptor isolated from Y-1 cells by an antibody to HTCA peptide, a complementary peptide to ACTH, wherein the receptor was tested for its capability of binding ACTH (page 1374, the second paragraph of the right column). Additionally, Bost's ACTH receptor seems to be a complete receptor with ligand binding activity as it binds ACTH and has a MW of 80,000 to 130,000, which is similar to the 100,000 previously reported for the ACTH receptor by a separate group. In contrast, neither the functional test nor the complete receptor sequence has been achieved for the present peptide of SEQ ID NO:2. Therefore, regardless how applicants arrive at the subject matter or how to isolated the peptide, the key issue remains whether the partial sequence of said "TMOF receptor" peptide possesses the ligand-binding property. However, the present declaration has not provided any evidence to address such, and therefore it insufficient to overcome the rejections of the claims under 35 U.S.C. 101 and 112, first paragraph.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-29 remain rejected, and the new claims 39-50 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, for the reasons of record set forth in the last Office Action mailed on 03 May 2004, at pages 2-3, and for the reasons above.

Applicants argument filed on 12 October 2004 has been fully considered, but is not deemed persuasive for reasons below.

At pages 5-6 of the response, the applicant argues that the Office has not provided sufficient evidence showing that one of ordinary skill in the art would doubt the asserted utility, and that as outlined in the Declaration, the nucleotide sequence of SEQ ID NO:1 was isolated from a cDNA library of the mosquito, and given the well-known experimental methods utilized, there is no reason to doubt that the corresponding amino acid sequence set forth as SEQ ID NO:2 exhibits the binding properties of the TMOF receptor. This argument is not persuasive because the major issue is not how and from which insect the SEQ ID NO:1 was isolated, nor whether a TMOF receptor would be useful for identifying an insecticidal compound, rather, as addressed in the last Office Action, the issue is that the disclosed SEQ ID NO:2 merely represents a partial sequence (62 amino acids) of a TMOF receptor, and the there is no evidence in the specification that this fragment was ever tested for its ligand binding activity. Further, the prior art sequence search does not reveal any family member with reasonable sequence homology. Therefore, due to lack of any evidence that the present SEQ ID NO:2 would bind a TMOF receptor ligand, and in the absence of a reference of any TMOF receptor sequence that would allow a determinant on based on homology, it is unclear whether the present SEQ ID NO:2 is a portion TMOF receptor, and which portion of the receptor it represents if it is a part of a "TMOF receptor", and whether this portion possesses the ligand binding property. These questions cannot be answered by the present disclosure.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-29 remain rejected, and the new claims 39-50 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make/use the claimed invention, for

the reasons of record set forth in the last Office Action mailed on 03 May 2004, at page 3, and for the reasons above.

Applicants argument filed on 12 October 2004 has been fully considered, but is not deemed persuasive for reasons below.

At page 6 of the response, the applicant argues that given the disclosure of the subject application, one of ordinary skill in the art would be able to make and use the invention using methods well known in the art, that applicants declaration also explains the method used to isolate the cDNA, and provides further evidence of the utility and enablement of the subject invention, and that in satisfying the enablement requirement, an application needs not teach and preferably omits, that which is well-known in the art. This argument is not persuasive because, as addressed above, even though the "complementary peptide approach" may represent an alternative way for sequence prediction and receptor synthesis, confirmation of TMOF binding capability would be necessary, as the present SEQ ID NO:2 is not the real sequence of a TMOF receptor, the art has not established that such an approach is predictable for all receptor-ligand binding, and experimental confirmation has been demonstrated in the prior art references. Thus, the method of isolation of the cDNA does not automatically confer the utility to the isolated cDNA or the polypeptide encoded thereby. Undue experimentation would be require for the skilled artisan prior to practicing the invention as claimed.

Further, even if there were utility and enablement for the polypeptide of SEQ ID NO:2, enablement would remain not to be commensurate in scope with claims 25-28, which are directed to a method for identifying a compound binding to any or all TMOF receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims, for the reasons of record set forth in the last Office Action mailed on 03 May 2004, at pages 3-4.

Further, claims 25-28 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention, for the reasons of record set forth in the last Office Action mailed on 03 May 2004, at page 4.

Applicants declaration and argument filed on 12 October 2004 has been fully considered, but is not deemed persuasive for reasons below.

At page 6 of the response, the applicant argues that applicant is not teaching new methods of genetic manipulation, nor is the applicant teaching the need to discover new genes, rather, the applicant is teaching the application of known techniques to a previously unknown nucleotide sequence, and that all the essential information is provided within the subject application to identify homologous TMOF receptors in other organisms. This argument is not persuasive because the present claims, *as written*, read on a method that requires a TMOF receptor ("contacting a candidate compound with a TMOF receptor", claim 25), which encompasses any and all possible TMOF receptor, and the specification never discloses one that is a complete functional TMOF receptor. The specification merely discloses a small peptide fragment generated by complementary peptide approach, and its ligand binding capability to TMOF or analog thereof has never been tested. Additionally, given the fact that the prior art sequence search does not reveal any peptide with reasonable homology to the present SEQ ID NO:2, there is no way for a skilled artisan to envision the detailed chemical structure of the encompassed TMOF receptors. Indeed, the discovery of new TMOF genes would be useful in supporting the present claims to meet the written description requirement under 35 U.S.C. 112, first paragraph, which is not taught in the instant application, as admitted by applicants that the applicant is not teaching the need to discover new genes.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 is indefinite for the recitation of "said polynucleotide is expressed at the surface of said host cell". "Said polypeptide is expressed at the surface of said host cell" is suggested.

Claim 50 is indefinite for the recitation of "a formulated product" because it is unclear how the product is formulated and what ingredient, in addition to said candidate compound, is incorporated.

Conclusion:

No claim is allowed.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
2/14/05